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09/707,589	11/07/2000	Christopher Perry	S-50035P1	9684

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EXAMINER	
MEHTA, ASHWIN D	
ART UNIT	PAPER NUMBER
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/707,589

Applicant(s)

PERRY, CHRISTOPHER

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Specification

1. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, for example at page 17, line 22 and page 20, line 19. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

2. Claims 1, 2, 5, 15-18, 20-22, 26-28, 32-34, and 41 are objected.

Claims 1, 2, 18, and 40 are objected to for the inclusion of a blank line where the ATCC accession number should appear.

In line 2 of claim 5 and line 1 of claims 15 and 16: "a" should be replaced with --the--.

In line 1 of claims 7-14, 17, 18, 20-22, 26-28, 32-34, and 41: "A" should be replaced with --The--.

In claim 16, line 3, "plants" should be replaced with --the plant--.

In claim 18, line 1, after "claim 16," insert --wherein said plant is--.

Claims 20, 26, and 32 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Regarding claim 20: the claim attempts to limit the method of claim 19 by requiring the first parent maize plant to be different from the

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second parent maize plant. However, claim 19 already requires the parent maize plants to be different. Lines 2-3 of claim 19 states that the first or (emphasis added) second parent maize plant is the maize plant of claim 2. The "or" indicates that only one of the parent plants is the plant of claim 2. As the parent plants of claim 19 are different, the method of claim 19 will also produce F1 hybrid seed. Claims 26 and 32 fail to limit the claims from which they depend for the same reasons. It is suggested that, in claims 19, 25, and 31, line 3, "or" be replaced with --and/or--.

Claims 21, 22, 27, 28, 33, and 34 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Claims 21 and 22 were examined as if the recitation "inbred maize plant of claim 2 is the female parent" read --the female (male) parent is the maize plant of inbred line NP2052--. Claims 27 and 28 were examined as if the corresponding recitation read --the female (male) parent is said inbred maize plant-- (also see the suggested amendment to claim 5 below). Claims 33 and 34 were examined as if the female (male) parent of the corresponding recitation referred to a maize plant of line NP2052 further comprising one or more single gene traits.

In claim 37, line 4, it is suggested that the recitation "plant according to claim 2" be replaced with --maize plant of line NP2052--.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 1-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "NP2052" in claims 1, 2, 18, 40, and 42 render the claims and those dependent thereon indefinite. Since the name "NP2052" is not known in the art, the use of said name does not carry art recognized limitations as to the specific characteristics or essential characteristics which are associated with that denomination. The name "NP2052" does not clearly identify the claimed maize inbred and seed, and does not set forth the metes and bounds of the claimed invention. In addition, the name appears to be arbitrary and the specific characteristics associated therewith could be modified. Amending claims 1, 2, 18, and 40 to recite the ATCC deposit number under which seed of maize inbred line NP2052 has been deposited would overcome the rejection.

In claim 10: the claim is a "Markush"-type claim that employs incorrect Markush terminology. It is suggested that, in line 2, --herbicide, a-- be inserted after "sulfonylurea", and "or an" be deleted.

In claim 17: the recitation "or being protoplasts or callus derived therefrom" renders the claim indefinite. It is not clear whether the recitation is referring to protoplasts or callus that are derived from the regenerable cells, or whether the regenerable cells can also be selected from the protoplasts or callus. If it is the latter, the following amendments are suggested: in line 1, replace the recitation "the regenerable cells being selected from the group" with --wherein the regenerable cells are selected from a) the group of plant parts--, and in line 3, replace "being" with --b)-- and replace "therefrom" with --from one of said plant parts--.

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In claim 25, 27, and 28: the recitation "inbred maize plant" in line 3 of claim 25 and line 1 of claims 27 and 28 render the claims indefinite. There is insufficient antecedent basis for this recitation. It is suggested that in claim 5, line 1, "A" be replaced with --An inbred--.

In claims 31, 33, and 34: the recitation "inbred maize plant of claim 7" in line 3 of claim 31 and line 1 of claims 33 and 34 lack sufficient antecedent basis. Further, the plant of claim 7 is not an inbred. It is suggested that "inbred" in line 3 of claim 31 be deleted.

In claim 38: the recitation "said one parent" renders the claim indefinite. It is not clear whether the recitation is referring to parent that is the "plant according to claim 2 or a maize plant having all of the morphological and physiological characteristics of a plant according to claim 2" mentioned in lines 2-4 of claim 37, or whether "said one parent" is the other parent.

In claim 42: the recitations "acceptable", "good", "early", "reliable", "improved", "acceptable", "above average" are relative terms and, when not associated with a specific numerical value, have no definite meaning. These recitations do not reasonably apprise one of the scope of the invention. Further still, the reference to the Northern Cornbelt regions of the United States also makes the claim indefinite, since the specification does not define the states, or the geographical portions of the states, that are found within these regions.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 42 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is broadly drawn towards NP2052-derived maize plant, or parts thereof, wherein at least one ancestor of said maize plant is the maize plant of claim 2 and expresses a combination of at least 2 NP2052 traits listed in the claim.

The specification describes the morphological and physiological characteristics of a maize inbred plant, arbitrarily given the designation NP2052 (page 10, Table 1 to page 16, seventh full paragraph).

However, the specification does not describe the plants wherein at least one ancestor is NP2052 and has as little as any two of the traits listed in the claim. The description of NP2052 is not indicative of a plant produced by crossing it with a plant of unknown genotype and phenotype and separated from NP2052 from an unknown number of generations. The claimed invention encompasses plants that express at least two of the listed "NP2052 traits." However, to say that a plant expresses two traits of another plant, or has two traits derived from another plant, is not sufficient information to describe that plant, as numerous corn plants express at least two of the same traits as NP2052. Two plant traits do not provide any information regarding any of the other traits. Therefore, to say that a plant expresses two NP2052 traits is not an indication that it was derived from NP2052, and it is not a sufficient description of that plant. Further, it is

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possible that the claimed plants inherited the genes governing those traits from an ancestor other than NP2052. Benson (U. S. Patent No. 6,087,566) describes a maize plant, designated "34F40," which at least two traits in common with NP2052, early pollen shed and an approximate relative maturity of 109 (col. 11, line 7 to col. 12, line 7). The instantly claimed maize plant could have 34F40 as an ancestor, as well as NP2052, in which case its relative maturity and early pollen shed traits could derived from 34F40, and considered 34F40 traits. Given the breadth of the claims encompassing maize plants expressing at least two traits listed in the claim, and lack of guidance as discussed above, the specification fails to provide an adequate written description of the multitude of corn plants and their parts encompassed by the claims.

5. Claims 1-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims broadly encompass a plant, or parts thereof, having characteristics of maize inbred line NP2052; seed or hybrids derived from NP2052; maize plants derived from NP2052; tissue culture derived from NP2052; methods of using NP2052 to produce hybrid maize seed or progeny; or NP2052-derived plants.

Since the seed, plants, and plant parts claimed are essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If seed of NP2052 is not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit thereof. The specification does not disclose a repeatable process to obtain the exact same seed in each occurrence and it is not apparent if such

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a seed is readily available to the public. It is noted that applicants intend to deposit seeds for NP2052 at the ATCC, but there is no indication that the seeds have been deposited.

If the deposit of these seeds is made under the terms of the Budapest Treaty, then an affidavit or declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the seeds will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must be maintained.

If the deposit will not be made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

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Claim Rejections - 35 USC § 102 & 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-11, 15-20, 23-26, 29-32, 35, 36, 40, and 42 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Benson (U.S. Patent No. 6,087,566).

The claims broadly encompass a plant, or parts thereof, having characteristics of maize inbred line NP2052; seed or hybrids derived from NP2052; maize plants derived from NP2052;

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tissue culture derived from NP2052; methods of using NP2052 to produce hybrid maize seed or progeny; or NP2052-derived plants.

Benson teaches maize line 34F40. It appears that the claimed plant and plant parts of the instant invention may be the same as the prior art maize line 34F40 and its parts, given that, for example, 34F40 has early pollen shed and a relative maturity of approximately 109 days, which is approximately 85-107 days (col. 11, line 7 to col. 12, line 7). Benson also teaches a maize plant produced from tissue culture of regenerable cells from various tissues of 34F40, and plants regenerated from the cells (col. 29, lines 14-44; claims). Benson also teaches crossing 34F40, or 3F40 comprising comprising a transgene, with itself or another maize plant to produce F1 hybrid plants and seed; manipulation to confer male sterility; introduction of genes into 34F40 that encode specific products and traits, including those that confer resistance to pests, diseases, herbicides such as glyphosate; operatively linking regulatory elements to transgenes; use of markers for selection, and using backcrossing to introgress a transgene into an inbred (col. 1, line 10 to col. 2, line 59; col. 29, line 45 to col. 37, line 65; col. 37, line 65 to col. 38, line 14; claims). Alternatively, if the claimed plants, plant parts, and seeds of NP2052 are not identical to 34F40 and hence anticipated by Benson, then the claimed plants, plant parts, and seeds are obvious over line 34F40 of Benson, due to minor morphological variation, wherein said minor morphological variation would be expected to occur in different progeny of the same line, and wherein said minor morphological variation would not confer a patentable distinction to NP2052. As line 34F40 shares physiological and morphological characteristics with line NP2052, the claimed invention was *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, if not anticipated by Benson. Amending claims 1, 2, 18, and 40 to include the ATCC

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accession number will overcome the rejection for claims 1-11, 15-20, 23-26, 29-32, 35, 36, and 40.

However, even with the inclusion of the ATCC number, the plants of claim 42 are still taught by and/or obvious over Benson, as line 34F40 expresses at least two of the characteristics listed in the claim, early pollen shed and relative maturity of approximately 85 to 105 days, for example. The process of making the claimed plants does not distinguish the plants themselves from those taught by the reference. See In re Thorpe, 227 USPQ 964,966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. Thus, the claimed invention was clearly prima facie obvious as a whole to one of ordinary skill in the art, if not anticipated by Benson.

7. Claims 1-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benson (U.S. Patent No. 6,087,566) in view of Plaisted et al. (U.S. Patent No. 5,990,395).

The claims broadly encompass a plant, or parts thereof, having characteristics of maize inbred line NP2052; seed or hybrids derived from NP2052; maize plants derived from NP2052; tissue culture derived from NP2052; methods of using NP2052 to produce hybrid maize seed or progeny; or NP2052-derived plants. The rejection addresses the claim limitations defining the female or male parent of the claimed methods; single gene traits conferred by the Cry1Ab gene, a bar gene, or introgressing the Cry1Ab gene by crossing with a maize plant comprising a 176 or Bt-11 event; and a method comprising growing hybrid and inbred seed and selecting inbred plants.

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Benson is discussed above.

Benson does not teach the *Bacillus thuringiensis* Cry1Ab gene, a bar gene, maize plants comprising a Bt-11 or 176 event. Benson also does not expressly teach defining the female and male parent in a cross, or growing hybrid and inbred corn seeds together and identifying and selecting the inbred plant.

Plaisted et al. teach the corn line W1498A; method for producing seed comprising crossing W1498A with another corn plant, wherein W1498A can be the female or male parent; introgression of single gene traits into W1498A, including wherein the trait is insect resistance conferred by the *B. thuringiensis* Cry1Ab gene into the corn plant, wherein the introgression is by transformation or from a maize line with a Bt-11 or 176 event; W148A further comprising the bar gene; expressing a bar gene to confer tolerance to the herbicide phosphinothricin or glufosinate; a method comprising a) planting a collection of seed comprising inbred W1498A and seed of a hybrid, one of whose parents is W1498A or has the physiological and morphological characteristics of W1498A, b) growing plants from said collection of seed, c) identifying and selecting the inbred plants, and controlling pollination in a manner which preserves the homozygosity of said inbred; said method wherein the parent having all the physiological and morphological characteristics of W1498A further comprises at least one single gene transferred trait; said method comprising identifying the inbred plants with decreased vigor (col. 10, line 59 to col. 11, line 13; col. 11, lines 27-30; claims).

It would have been obvious and within the scope of one of ordinary skill in the art at the time the invention was made to modify the plants and methods of Benson by introducing genes into NP2052 or into plants having all of the morphological and physiological characteristics of

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NP2052, wherein the genes confer desirable single gene traits, such as the Cry1Ab and bar genes, as taught by Plaisted et al. One would do so using the methods taught by Plaisted et al. It would also have been obvious to grow plants from a collection of seeds comprising NP2052 and a hybrid, one of whose parents is NP2052 or plant that has all of the physiological and morphological characteristics of NP2052, and identify the inbred plants by their decreased vigor, following the teachings of Plaisted et al. One would be motivated to follow such a method, as this eliminates the step of having to separate seeds in a seed collection. One would obviously be motivated to introgress Cry1Ab and the bar genes into NP2052, as they confer desirable traits of insect and herbicide resistance, respectively. The invention is *prima facie* obvious as a whole, in the absence of evidence to the contrary.

8. No claim is allowed.

Contact Information

Any inquiry concerning this communication from the examiner should be directed to Ashwin D. Mehta whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M.. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general


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nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

January 28, 2002


ASHWIN D. MEHTA, PH.D
PATENT EXAMINER